Boston Scientific

Fathom™-16

Steerable Guidewire

Tổng giám đốc

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Boston Scientific (Master Brand DFUTemplate 8in x 8in Global, 90106041AK), DFU, MB, FATHOM-16, Global, 90962168-01A

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Fathom™ -16

Steerable Guidewire

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The FATHOM -16 Steerable Guidewire has a maximum diameter of 0.016 in (0.41 mm). The guidewire is compatible with existing microcatheters used in common endovascular procedures such as those for diagnosis and therapy in the peripheral vasculature.

For lubricity, the distal portion of the device is coated with a hydrophilic polymer and the proximal portion is coated with polytetrafluoroethylene (PTFE). The distal portion of the guidewire tip is radiopaque. The distal 2 cm (0.79 in) is shapeable/reshapeable.

The torque device included with the guidewire attaches to the proximal end of the guidewire and functions as a steering mechanism. Rotation of this device facilitates guidewire placement into the appropriate vessel by precise directional manipulation of the guidewire tip.

The guidewire introducer/shaping mandrel included with the device is intended to aid insertion of the guidewire into the catheter hub and/or hemostasis valve and/or shape the guidewire tip.

Contents

This package contains one guidewire, one torque device and one guidewire introducer/shaping mandrel.

INTENDED USE/INDICATIONS FOR USE

The FATHOM -16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

CONTRAINDICATIONS

None known.

ADVERSE EVENTS

Complications attributed to endovascular procedures are the following:

- Vessel trauma
- Vessel damage
- Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism)
- Pseudoaneurysm
- Seizure/stroke
- Vessel dissection
- Hematoma at the puncture site
- Nerve injury
- Infection
- Perforation of the vessel
- Vessel spasm
- Hemorrhage
- Vascular thrombosis
- Vessel occlusion
- Death
- Bleeding
- Failed treatment
- Inability to position guidewire
- Damage to the catheter

WARNINGS

Excessive force against resistance may result in separation of the guidewire tip.

The FATHOM Steerable Guidewire is not intended for use in the coronary vasculature or the neuro vasculature.

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PRECAUTIONS

	Distal Outside Diameter	Proximal Outside Diameter	Compatible Microcatheters
FATHOM™ -16 Steerable Guidewire	0.016 in (0.41 mm) Maximum	0.016 in (0.41 mm) Maximum	Microcatheters with ID 0.021-0.027 in (0.53 – 0.69 mm) e.g. Renegade™ HI-FLO™ Microcatheter, Renegade™ Fiber Braided Microcatheter, Renegade™ STC-18 Microcatheter

- Inspect guidewire prior to use for any surface irregularities and bends or kinks. Any guidewire damage may decrease the desired performance characteristics.
- When the guidewire is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the wire without observing the resultant tip response.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter, or vessel perforation.
- Exercise care in handling a guidewire during a procedure to reduce the possibility of accidental breakage, bending or kinking. Do not use a guidewire that has been damaged.
- To avoid guidewire damage and possible shearing of plastic, do not withdraw or manipulate the guidewire through a metal needle cannula.
- Excessive tightening of the torque device onto the wire may result in abrasion of the coating of the wire.
- The Boston Scientific guidewire, the guidewire insertion tool, and the torque device are supplied STERILE and non-pyrogenic in unopened, undamaged packages. Verify that the sterility of the device has not been compromised by assuring package integrity has been maintained.
- If the integrity of the packaging has been compromised, **do not use or attempt to resterilize.** Contact your local Boston Scientific representative.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Check labeled diameter of diagnostic or therapeutic catheter and verify compatibility with the guidewire outer diameter prior to use.
- Due to the variations of certain catheter tip inner diameters, abrasion of the hydrophilic coating may occur during manipulation. If any resistance is felt during introduction of the catheter, use of a different catheter may be warranted.
- Neither the guidewire insertion tool, nor the torque device are intended to enter the body.
- If other interventional devices are used with the FATHOM -16 Steerable Guidewire, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device. Verify that package integrity has not been compromised prior to use. Do not use a product after the expiration date.
- It is recommended that a continuous saline flush be maintained between the guiding catheter and the interventional device and between the interventional device and the guidewire during the procedure. Flushing prevents contrast crystal formation and/or clotting on the guidewire and in the catheter lumen.

OPERATIONAL INSTRUCTIONS

Preparations For Use

1. Flush packaging hoop with heparinized saline solution in order to hydrate the guidewire coating. Once the product is hydrated, do not allow the product to dry.
2. Carefully remove guidewire from protective packaging hoop. Examine prior to use for evidence of bends, kinks or other damage.
3. Carefully shape the guidewire tip per the following instructions:
   - Hold the guidewire introducer (included) or equivalent shaping tool in one hand and rest the guidewire tip across the wire introducer or shaping tool at a 90° angle.
   - Gently pinch the guidewire tip between the guidewire introducer or tool and thumb.
   - Carefully pull the mandrel toward the guidewire distal tip to implement shape.
   - Repeat as needed to achieve desired shape.
   - Inspect the shaped tip carefully for any damage. If damaged, do not use the guidewire.

Directions For Use

1. Prior to inserting the guidewire into a microcatheter, flush the catheter with heparinized saline. This will prime the catheter and provide for smooth movement of the guidewire within the catheter.
2. Carefully insert the guidewire tip into the microcatheter and advance the guidewire being careful not to damage the guidewire tip. The guidewire introducer may be used to facilitate the introduction of the guidewire into hemostatic valves and catheter hubs.
3. If desired, put the torque device on the guidewire by slipping the device over the proximal end of the guidewire. When the torque device is in the desired location, tighten the cap to secure the device in place. The torque device may be repositioned or removed as required.
4. Carefully advance and rotate the guidewire under fluoroscopy to select the appropriate vessel.
5. Advance the guidewire and microcatheter to a selected vascular site by alternately advancing the guidewire and then tracking the microcatheter over the guidewire.
   5.1. Keep guidewire hydrated during the procedure.
6. Completely remove the guidewire from the microcatheter.

HOW SUPPLIED

Packaging is designed to maintain sterility according to the expiration date on the label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.